

Valaciclovir 500 mg film-coated tablets

(valaciclovir hydrochloride)

Your medicine is known by the above name, but will be referred to as Valaciclovir throughout this leaflet.

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

- 1) What Valaciclovir is and what it is used for
- 2) What you need to know before you take Valaciclovir
- 3) How to take Valaciclovir
- 4) Possible side effects
- 5) How to store Valaciclovir
- 6) Contents of the pack and other information

1) What Valaciclovir is and what it is used for

Valaciclovir contains the active substance valaciclovir hydrochloride, hydrate. Valaciclovir belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

Valaciclovir can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)
- treat HSV infections of the eye that continue to come back (in adults and adolescents over 12 years old).

2) What you need to know before you take Valaciclovir

Do not take Valaciclovir

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in Section 6).
- if you have ever developed an extended rash associated with fever, enlarged lymph node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.

If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valaciclovir if:

- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking valaciclovir and contact your doctor or seek medical attention immediately.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Valaciclovir.

Prevent passing genital herpes on to others

If you are taking Valaciclovir to treat genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Children under 12 years of age

This medicine is not recommended for children under 12 years of age.

Other medicines and Valaciclovir

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking Valaciclovir for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valaciclovir is not usually recommended for use during pregnancy. If you are pregnant, or think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking Valaciclovir. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir while you are pregnant or breastfeeding.

Driving and using machines

Valaciclovir may cause side effects that affect your ability to drive. Do not drive or use machines unless you are sure you are not affected.

3) How to take Valaciclovir

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on why your doctor has prescribed Valaciclovir for you. Your doctor will discuss this with you.

Treatment of shingles

- The recommended dose is 1000 mg (two 500 mg tablets) three times a day.
- You should take Valaciclovir for seven days.

Treatment of cold sores

- The recommended dose is 2000 mg (four 500 mg tablets) twice a day.
- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose.
- You should take Valaciclovir for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The recommended dose is 500 mg (one 500 mg tablet) twice a day.
- For the first infection you should take Valaciclovir for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them

- The recommended dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250 mg tablet twice a day. For doses less than 500 mg, Valaciclovir 500 mg Film-coated Tablets are not suitable. Lower strengths of other valaciclovir medicinal products are available. Your doctor will advise you accordingly.
- You should take Valaciclovir until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)

- The recommended dose is 2000 mg (four 500 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Valaciclovir as soon as possible after your surgery.
- You should take Valaciclovir for around 90 days after your surgery, until your doctor tells you to stop.

Children under 12 years of age

Valaciclovir is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy.

Your doctor may adjust the dose of Valaciclovir if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems

Talk to your doctor before taking Valaciclovir if any of the above apply.

Method of administration

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valaciclovir at the same time each day.
- Take Valaciclovir according to instructions from your doctor or pharmacist.

People over 65 years of age or with kidney problems

It is very important while you are taking Valaciclovir that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you take more Valaciclovir than you should

Valaciclovir is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy, see, feel or hear things that are not there (hallucinations), have kidney problems where you pass little or no urine or lose consciousness (coma). Talk to your doctor or pharmacist if you take too much Valaciclovir. Take the medicine pack with you.

If you forget to take Valaciclovir

- If you forget to take Valaciclovir, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

If you stop taking Valaciclovir

Do not stop taking this medicine without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4) Possible side effects

Like all medicines, Valaciclovir can cause side effects, although not everybody gets them.

The side effects usually occur in the beginning of treatment and become milder or stop altogether within a few weeks. Sometimes it is difficult to tell the difference between symptoms of an illness and side effects.

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately:

Rare (may affect up to 1 in 1,000 people)

- severe allergic reactions (anaphylaxis). Rapid development of symptoms including:
 - flushing, itchy skin rash
 - swelling of the lips, face, neck and throat, causing difficulty in breathing (angioedema)
 - fall in blood pressure leading to collapse.
- kidney problems where you pass little or no urine
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts (psychoses).

Not known (cannot be estimated from available data)

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.
- an inflammation of the kidneys (tubulointerstitial nephritis).

Other side effects include:

Very Common (may affect more than 1 in 10 people)

- headache

Common (may affect up to 1 in 10 people)

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (photosensitivity)
- rash.

Uncommon (may affect up to 1 in 100 people)

- feeling confused
- seeing or hearing things that aren't there (hallucinations)
- feeling very drowsy
- tremors
- feeling agitated.

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir a day. They usually get better when Valaciclovir is stopped or the dose reduced.

Other uncommon side effects:

- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)
- blood in the urine.

Uncommon side effects that may show up in blood tests:

- reduction in the number of white blood cells (leucopenia)
- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver.

Rare (may affect up to 1 in 1,000 people)

- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir a day. They usually get better when Valaciclovir is stopped or the dose reduced.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Valaciclovir

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date printed on the carton or blister label. The expiry date refers to the last day of the month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Valaciclovir contains:

The active substance is valaciclovir hydrochloride. Each tablet contains 500mg of valaciclovir (as hydrochloride hydrate). The other ingredients in the tablet core are: cellulose, microcrystalline; crospovidone; povidone K90 and magnesium stearate. The ingredients in the coating (Opadry YS-1R-7003) are: titanium dioxide (E171); macrogol 400; polysorbate 80 and hypromellose 3cps and hypromellose 5cps

What Valaciclovir looks like and contents of the pack

Valaciclovir are white to off-white, capsule-shaped, biconvex film-coated tablets with "VC 500" on one side and "G" on the other side.

They are available in blister packs containing 10 and 42 tablets.

PL 46420/0489 Valaciclovir 500mg film-coated tablets **POM**

Who makes and repackages your medicine?

Your medicine is manufactured by Mylan Hungary Kft, H-2900 Komarom, Mylan utca 1, Hungary. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 21.02.2024

For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.

Valaciclovir Viatris® 500 mg film-coated tablets

(valaciclovir hydrochloride)

Your medicine is known by the above name, but will be referred to as Valaciclovir Viatris throughout this leaflet.

Patient Information Leaflet

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- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

- 1) What Valaciclovir Viatris is and what it is used for
- 2) What you need to know before you take Valaciclovir Viatris
- 3) How to take Valaciclovir Viatris
- 4) Possible side effects
- 5) How to store Valaciclovir Viatris
- 6) Contents of the pack and other information

1) What Valaciclovir Viatris is and what it is used for

Valaciclovir Viatris contains the active substance valaciclovir hydrochloride, hydrate. Valaciclovir Viatris belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

Valaciclovir Viatris can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)
- treat HSV infections of the eye that continue to come back (in adults and adolescents over 12 years old).

2) What you need to know before you take Valaciclovir Viatris

Do not take Valaciclovir Viatris

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in Section 6).
- if you have ever developed an extended rash associated with fever, enlarged lymph node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking Valaciclovir Viatris.

If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir Viatris.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valaciclovir Viatris if:

- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking Valaciclovir Viatris and contact your doctor or seek medical attention immediately.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Valaciclovir Viatris.

Prevent passing genital herpes on to others

If you are taking Valaciclovir Viatris to treat genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Children under 12 years of age

This medicine is not recommended for children under 12 years of age.

Other medicines and Valaciclovir Viatris

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking Valaciclovir Viatris for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valaciclovir Viatris is not usually recommended for use during pregnancy. If you are pregnant, or think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking Valaciclovir Viatris. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir Viatris while you are pregnant or breastfeeding.

Driving and using machines

Valaciclovir Viatris may cause side effects that affect your ability to drive. Do not drive or use machines unless you are sure you are not affected.

3) How to take Valaciclovir Viatris

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on why your doctor has prescribed Valaciclovir Viatris for you. Your doctor will discuss this with you.

Treatment of shingles

- The recommended dose is 1000 mg (two 500 mg tablets) three times a day.
- You should take Valaciclovir Viatris for seven days.

Treatment of cold sores

- The recommended dose is 2000 mg (four 500 mg tablets) twice a day.
- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose.
- You should take Valaciclovir Viatris for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The recommended dose is 500 mg (one 500 mg tablet) twice a day.
- For the first infection you should take Valaciclovir Viatris for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them

- The recommended dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250 mg tablet twice a day. For doses less than 500 mg, Valaciclovir Viatris 500 mg Film-coated Tablets are not suitable. Lower strengths of other Valaciclovir medicinal products are available. Your doctor will advise you accordingly.
- You should take Valaciclovir Viatris until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)

- The recommended dose is 2000 mg (four 500 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Valaciclovir Viatris as soon as possible after your surgery.
- You should take Valaciclovir Viatris for around 90 days after your surgery, until your doctor tells you to stop.

Children under 12 years of age

Valaciclovir Viatris is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy.

Your doctor may adjust the dose of Valaciclovir Viatris if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems

Talk to your doctor before taking Valaciclovir Viatris if any of the above apply.

Method of administration

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valaciclovir Viatris at the same time each day.
- Take Valaciclovir Viatris according to instructions from your doctor or pharmacist.

People over 65 years of age or with kidney problems

It is very important while you are taking Valaciclovir Viatris that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you take more Valaciclovir Viatris than you should

Valaciclovir Viatris is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy, see, feel or hear things that are not there (hallucinations), have kidney problems where you pass little or no urine or lose consciousness (coma). Talk to your doctor or pharmacist if you take too much Valaciclovir Viatris. Take the medicine pack with you.

If you forget to take Valaciclovir Viatris

- If you forget to take Valaciclovir Viatris, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

If you stop taking Valaciclovir Viatris

Do not stop taking this medicine without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4) Possible side effects

Like all medicines, Valaciclovir Viatris can cause side effects, although not everybody gets them.

The side effects usually occur in the beginning of treatment and become milder or stop altogether within a few weeks. Sometimes it is difficult to tell the difference between symptoms of an illness and side effects.

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately:

Rare (may affect up to 1 in 1,000 people)

- severe allergic reactions (anaphylaxis). Rapid development of symptoms including:
 - flushing, itchy skin rash
 - swelling of the lips, face, neck and throat, causing difficulty in breathing (angioedema)
 - fall in blood pressure leading to collapse.
- kidney problems where you pass little or no urine
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts (psychoses).

Not known (cannot be estimated from available data)

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.
- an inflammation of the kidneys (tubulointerstitial nephritis).

Other side effects include:

Very Common (may affect more than 1 in 10 people)

- headache

Common (may affect up to 1 in 10 people)

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (photosensitivity)
- rash.

Uncommon (may affect up to 1 in 100 people)

- feeling confused
- seeing or hearing things that aren't there (hallucinations)
- feeling very drowsy
- tremors
- feeling agitated.

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir Viatris a day. They usually get better when Valaciclovir Viatris is stopped or the dose reduced.

Other uncommon side effects:

- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)
- blood in the urine.

Uncommon side effects that may show up in blood tests:

- reduction in the number of white blood cells (leucopenia)
- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver.

Rare (may affect up to 1 in 1,000 people)

- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir Viatris a day. They usually get better when Valaciclovir Viatris is stopped or the dose reduced.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Valaciclovir Viatris

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date printed on the carton or blister label. The expiry date refers to the last day of the month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Valaciclovir Viatris contains:

The active substance is valaciclovir hydrochloride. Each tablet contains 500mg of valaciclovir (as hydrochloride hydrate). The other ingredients in the tablet core are: cellulose, microcrystalline; crospovidone; povidone K90 and magnesium stearate. The ingredients in the coating (Opadry YS-1R-7003) are: titanium dioxide (E171); macrogol 400; polysorbate 80 and hypromellose 3cps and hypromellose 5cps

What Valaciclovir Viatris looks like and contents of the pack

Valaciclovir Viatris are white to off-white, capsule-shaped, biconvex film-coated tablets with "VC 500" on one side and "G" on the other side.

They are available in blister packs containing 10 and 42 tablets.

PL 46420/0489 Valaciclovir Viatris 500mg film-coated tablets

POM

Who makes and repackages your medicine?

Your medicine is manufactured by Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 21.02.2024

Valaciclovir Viatris is a registered trademark holder of Mylan Inc., United States of America.

For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.

Valaciclovir Suerte 500 mg film-coated tablets

(valaciclovir hydrochloride)

Your medicine is known by the above name, but will be referred to as Valaciclovir Suerte throughout this leaflet.

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

- 1) What Valaciclovir Suerte is and what it is used for
- 2) What you need to know before you take Valaciclovir
- 3) How to take Valaciclovir Suerte
- 4) Possible side effects
- 5) How to store Valaciclovir Suerte
- 6) Contents of the pack and other information

1) What Valaciclovir Suerte is and what it is used for

Valaciclovir Suerte contains the active substance valaciclovir hydrochloride, hydrate. Valaciclovir Suerte belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

Valaciclovir Suerte can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)
- treat HSV infections of the eye that continue to come back (in adults and adolescents over 12 years old).

2) What you need to know before you take Valaciclovir Suerte

Do not take Valaciclovir Suerte

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in Section 6).
- if you have ever developed an extended rash associated with fever, enlarged lymph node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.

If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir Suerte.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valaciclovir Suerte if:

- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking valaciclovir and contact your doctor or seek medical attention immediately.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Valaciclovir Suerte.

Prevent passing genital herpes on to others

If you are taking Valaciclovir Suerte to treat genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Children under 12 years of age

This medicine is not recommended for children under 12 years of age.

Other medicines and Valaciclovir Suerte

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking Valaciclovir Suerte for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valaciclovir Suerte is not usually recommended for use during pregnancy. If you are pregnant, or think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking Valaciclovir Suerte. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir Suerte while you are pregnant or breastfeeding.

Driving and using machines

Valaciclovir Suerte may cause side effects that affect your ability to drive. Do not drive or use machines unless you are sure you are not affected.

3) How to take Valaciclovir Suerte

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on why your doctor has prescribed Valaciclovir Suerte for you. Your doctor will discuss this with you.

Treatment of shingles

- The recommended dose is 1000 mg (two 500 mg tablets) three times a day.
- You should take Valaciclovir Suerte for seven days.

Treatment of cold sores

- The recommended dose is 2000 mg (four 500 mg tablets) twice a day.
- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose.
- You should take Valaciclovir Suerte for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The recommended dose is 500 mg (one 500 mg tablet) twice a day.
- For the first infection you should take Valaciclovir Suerte for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them

- The recommended dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250 mg tablet twice a day. For doses less than 500 mg, Valaciclovir Suerte 500 mg Film-coated Tablets are not suitable. Lower strengths of other valaciclovir medicinal products are available. Your doctor will advise you accordingly.
- You should take Valaciclovir until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)

- The recommended dose is 2000 mg (four 500 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Valaciclovir Suerte as soon as possible after your surgery.
- You should take Valaciclovir Suerte for around 90 days after your surgery, until your doctor tells you to stop.

Children under 12 years of age

Valaciclovir Suerte is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy.

Your doctor may adjust the dose of Valaciclovir Suerte if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems

Talk to your doctor before taking Valaciclovir if any of the above apply.

Method of administration

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valaciclovir Suerte at the same time each day.
- Take Valaciclovir Suerte according to instructions from your doctor or pharmacist.

People over 65 years of age or with kidney problems

It is very important while you are taking Valaciclovir Suerte that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely

monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you take more Valaciclovir Suerte than you should

Valaciclovir Suerte is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy, see, feel or hear things that are not there (hallucinations), have kidney problems where you pass little or no urine or lose consciousness (coma). Talk to your doctor or pharmacist if you take too much Valaciclovir Suerte. Take the medicine pack with you.

If you forget to take Valaciclovir Suerte

- If you forget to take Valaciclovir Suerte, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

If you stop taking Valaciclovir Suerte

Do not stop taking this medicine without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4) Possible side effects

Like all medicines, Valaciclovir Suerte can cause side effects, although not everybody gets them.

The side effects usually occur in the beginning of treatment and become milder or stop altogether within a few weeks. Sometimes it is difficult to tell the difference between symptoms of an illness and side effects.

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately:

Rare (may affect up to 1 in 1,000 people)

- severe allergic reactions (anaphylaxis). Rapid development of symptoms including:
 - flushing, itchy skin rash
 - swelling of the lips, face, neck and throat, causing difficulty in breathing (angioedema)
 - fall in blood pressure leading to collapse.
- kidney problems where you pass little or no urine
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts (psychoses).

Not known (cannot be estimated from available data)

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.
- an inflammation of the kidneys (tubulointerstitial nephritis).

Other side effects include:

Very Common (may affect more than 1 in 10 people)

- headache

Common (may affect up to 1 in 10 people)

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (photosensitivity)
- rash.

Uncommon (may affect up to 1 in 100 people)

- feeling confused
- seeing or hearing things that aren't there (hallucinations)
- feeling very drowsy
- tremors
- feeling agitated.

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir Suerte a day. They usually get better when Valaciclovir Suerte is stopped or the dose reduced.

Other uncommon side effects:

- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)
- blood in the urine.

Uncommon side effects that may show up in blood tests:

- reduction in the number of white blood cells (leucopenia)

- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver.

Rare (may affect up to 1 in 1,000 people)

- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir Suerte a day. They usually get better when Valaciclovir is stopped or the dose reduced.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Valaciclovir Suerte

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date printed on the carton or blister label. The expiry date refers to the last day of the month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

What Valaciclovir Suerte contains:

The active substance is valaciclovir hydrochloride. Each tablet contains 500mg of valaciclovir (as hydrochloride hydrate). The other ingredients in the tablet core are: cellulose, microcrystalline; crospovidone; povidone K90 and magnesium stearate. The ingredients in the coating (Opadry YS-1R-7003) are: titanium dioxide (E171); macrogol 400; polysorbate 80 and hypromellose 3cps and hypromellose 5cps

What Valaciclovir Suerte looks like and contents of the pack

Valaciclovir Suerte are white to off-white, capsule-shaped, biconvex film-coated tablets with "VC 500" on one side and "G" on the other side.

They are available in blister packs containing 10 and 42 tablets.

PL 46420/0489 Valaciclovir Suerte 500mg film-coated tablets

POM

Who makes and repackages your medicine?

Your medicine is manufactured by Mylan Hungary Kft, H-2900 Komárom, Mylan utca 1, Hungary. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

Leaflet date: 21.02.2024

For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.

Valaciclovir Mylan® 500 mg film-coated tablets

(valaciclovir hydrochloride)

Your medicine is known by the above name, but will be referred to as Valaciclovir Mylan throughout this leaflet.

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

- 1) What Valaciclovir Mylan is and what it is used for
- 2) What you need to know before you take Valaciclovir
- 3) How to take Valaciclovir Mylan
- 4) Possible side effects
- 5) How to store Valaciclovir Mylan
- 6) Contents of the pack and other information

1) What Valaciclovir Mylan is and what it is used for

Valaciclovir Mylan contains the active substance valaciclovir hydrochloride, hydrate. Valaciclovir Mylan belongs to a group of medicines called antivirals. It works by killing or stopping the growth of viruses called herpes simplex (HSV), varicella zoster (VZV) and cytomegalovirus (CMV).

Valaciclovir Mylan can be used to:

- treat shingles (in adults)
- treat HSV infections of the skin and genital herpes (in adults and adolescents over 12 years old). It is also used to help prevent these infections from returning.
- treat cold sores (in adults and adolescents over 12 years old)
- prevent infection with CMV after organ transplants (in adults and adolescents over 12 years old)
- treat HSV infections of the eye that continue to come back (in adults and adolescents over 12 years old).

2) What you need to know before you take Valaciclovir Mylan

Do not take Valaciclovir Mylan

- if you are allergic to valaciclovir or aciclovir or any of the other ingredients of this medicine (listed in Section 6).
- if you have ever developed an extended rash associated with fever, enlarged lymph node, increased levels of liver enzymes and/or eosinophilia (drug reaction with eosinophilia and systemic symptoms) after taking valaciclovir.

If you are not sure, talk to your doctor or pharmacist before taking Valaciclovir Mylan.

Warnings and precautions

Talk to your doctor or pharmacist before taking Valaciclovir Mylan if:

- you have kidney problems
- you have liver problems
- you are over 65 years of age
- your immune system is weak

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of valaciclovir. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes.

If you develop a rash associated with fever and enlarged lymph nodes, stop taking valaciclovir and contact your doctor or seek medical attention immediately.

If you are not sure if the above apply to you, talk to your doctor or pharmacist before taking Valaciclovir.

Prevent passing genital herpes on to others

If you are taking Valaciclovir Mylan to treat genital herpes, or you have had genital herpes in the past, you should still practice safe sex, including the use of condoms. This is important to prevent you passing the infection on to others. You should not have sex if you have genital sores or blisters.

Children under 12 years of age

This medicine is not recommended for children under 12 years of age.

Other medicines and Valaciclovir

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines.

Tell your doctor or pharmacist if you are taking any other medicines that affect the kidneys. These include: aminoglycosides, organoplatinum compounds, iodinated contrast media, methotrexate, pentamidine, foscarnet, ciclosporin, tacrolimus, cimetidine and probenecid.

Always tell your doctor or pharmacist about other medicines if you are taking Valaciclovir Mylan for treatment of shingles or after having an organ transplant.

Pregnancy and breast-feeding

Valaciclovir Mylan is not usually recommended for use during pregnancy. If you are pregnant, or think you may be pregnant, or are planning to have a baby, ask your doctor for advice before taking Valaciclovir Mylan. Your doctor will weigh up the benefit to you against the risk to your baby of taking Valaciclovir Mylan while you are pregnant or breastfeeding.

Driving and using machines

Valaciclovir Mylan may cause side effects that affect your ability to drive. Do not drive or use machines unless you are sure you are not affected.

3) How to take Valaciclovir Mylan

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The dose that you should take will depend on why your doctor has prescribed Valaciclovir Mylan for you. Your doctor will discuss this with you.

Treatment of shingles

- The recommended dose is 1000 mg (two 500 mg tablets) three times a day.
- You should take Valaciclovir Mylan for seven days.

Treatment of cold sores

- The recommended dose is 2000 mg (four 500 mg tablets) twice a day.
- The second dose should be taken 12 hours (no sooner than 6 hours) after the first dose.
- You should take Valaciclovir Mylan for one day (two doses) only.

Treatment of HSV infections of the skin and genital herpes

- The recommended dose is 500 mg (one 500 mg tablet) twice a day.
- For the first infection you should take Valaciclovir Mylan for five days or for up to ten days if your doctor tells you to. For recurrent infection the duration of treatment is normally 3-5 days.

Helping to prevent HSV infections from returning after you have had them

- The recommended dose is one 500 mg tablet once a day.
- Some people with frequent recurrences may benefit from taking one 250 mg tablet twice a day. For doses less than 500 mg, Valaciclovir Mylan 500 mg Film-coated Tablets are not suitable. Lower strengths of other valaciclovir medicinal products are available. Your doctor will advise you accordingly.
- You should take Valaciclovir until your doctor tells you to stop.

To stop you being infected with CMV (Cytomegalovirus)

- The recommended dose is 2000 mg (four 500 mg tablets) four times a day.
- You should take each dose about 6 hours apart.
- You will usually start taking Valaciclovir Mylan as soon as possible after your surgery.
- You should take Valaciclovir Mylan for around 90 days after your surgery, until your doctor tells you to stop.

Children under 12 years of age

Valaciclovir Mylan is not recommended for use in children below the age of 12 years due to insufficient data on safety and efficacy.

Your doctor may adjust the dose of Valaciclovir Mylan if:

- you are over 65 years of age
- you have a weak immune system
- you have kidney problems

Talk to your doctor before taking Valaciclovir if any of the above apply.

Method of administration

- Take this medicine by mouth.
- Swallow the tablets whole with a drink of water.
- Take Valaciclovir Mylan at the same time each day.
- Take Valaciclovir Mylan according to instructions from your doctor or pharmacist.

People over 65 years of age or with kidney problems

It is very important while you are taking Valaciclovir Mylan that you drink water regularly during the day. This will help to reduce side effects that can affect the kidney or nervous system. Your doctor will closely monitor you for signs of these. Nervous system side effects might include feeling confused or agitated, or feeling unusually sleepy or drowsy.

If you take more Valaciclovir Mylan than you should

Valaciclovir Mylan is not usually harmful, unless you take too much over several days. If you take too many tablets you may feel sick, vomit, or be confused, agitated or unusually sleepy, see, feel or hear things that are not there (hallucinations), have kidney problems where you pass little or no urine or lose consciousness (coma). Talk to your doctor or pharmacist if you take too much Valaciclovir Mylan. Take the medicine pack with you.

If you forget to take Valaciclovir Mylan

- If you forget to take Valaciclovir Mylan, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Don't take a double dose to make up for a forgotten dose.

If you stop taking Valaciclovir Mylan

Do not stop taking this medicine without consulting your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4) Possible side effects

Like all medicines, Valaciclovir can cause side effects, although not everybody gets them.

The side effects usually occur in the beginning of treatment and become milder or stop altogether within a few weeks. Sometimes it is difficult to tell the difference between symptoms of an illness and side effects.

If you think you may have any of the following side effects, stop taking this medicine and contact your doctor or go to your nearest hospital emergency room immediately:

Rare (may affect up to 1 in 1,000 people)

- severe allergic reactions (anaphylaxis). Rapid development of symptoms including:
 - flushing, itchy skin rash
 - swelling of the lips, face, neck and throat, causing difficulty in breathing (angioedema)
 - fall in blood pressure leading to collapse.
- kidney problems where you pass little or no urine
- fits (convulsions)
- altered brain function (encephalopathy)
- unconsciousness (coma)
- confused or disturbed thoughts (psychoses).

Not known (cannot be estimated from available data)

- Drug Reaction with Eosinophilia and Systemic Symptoms also known as DRESS or drug hypersensitivity syndrome, which is characterised by widespread rash, high body temperature, liver enzyme elevations, blood abnormalities (eosinophilia), enlarged lymph nodes and possibly other body organs involvement. See also section 2.
- an inflammation of the kidneys (tubulointerstitial nephritis).

Other side effects include:

Very Common (may affect more than 1 in 10 people)

- headache

Common (may affect up to 1 in 10 people)

- feeling sick
- dizziness
- vomiting
- diarrhoea
- skin reaction after exposure to sunlight (photosensitivity)
- rash.

Uncommon (may affect up to 1 in 100 people)

- feeling confused
- seeing or hearing things that aren't there (hallucinations)
- feeling very drowsy
- tremors
- feeling agitated.

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir a day. They usually get better when Valaciclovir Mylan is stopped or the dose reduced.

Other uncommon side effects:

- shortness of breath (dyspnoea)
- stomach discomfort
- rash, sometimes itchy, hive-like rash (urticaria)
- low back pain (kidney pain)
- blood in the urine.

Uncommon side effects that may show up in blood tests:

- reduction in the number of white blood cells (leucopenia)
- reduction in the number of blood platelets which are cells that help blood to clot (thrombocytopenia)
- increase in substances produced by the liver.

Rare (may affect up to 1 in 1,000 people)

- unsteadiness when walking and lack of coordination (ataxia)
- slow, slurred speech (dysarthria)

These nervous system side effects usually occur in people with kidney problems, the elderly or in organ transplant patients taking high doses of 8 grams or more of Valaciclovir Mylan a day. They usually get better when Valaciclovir is stopped or the dose reduced.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Valaciclovir Mylan

- Keep out of the sight and reach of children.
- Do not take this medicine after the expiry date printed on the carton or blister label. The expiry date refers to the last day of the month.
- This medicinal product does not require any special storage conditions.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6) Contents of the pack and other information

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What Valaciclovir Mylan looks like and contents of the pack

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They are available in blister packs containing 10 and 42 tablets.

PL 46420/0489 Valaciclovir Mylan 500mg film-coated tablets **POM**

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Leaflet date: 21.02.2024

Valaciclovir Mylan is a registered trademark holder of Mylan Inc., United States of America.

For any information about this medicine or to request a copy of this leaflet in Braille, large print or audio, please call the PL holder: Suerte Pharma Limited on 020 8839 3000.